HOUSE BILL No. 1672

DIGEST OF INTRODUCED BILL

Citations Affected: IC 34-6-2; IC 34-20-2; IC 34-30-16.5.

Synopsis: Immunity involving drugs and medical devices. Provides that manufacturers and sellers of drugs and medical devices are not subject to liability in a product liability action if: (1) the Food and Drug Administration (FDA) approved the drug or medical device as safe and effective; and (2) the FDA approval was in effect when the drug or medical device was sold to or for use by a user or consumer who was injured by the drug or medical device. Provides that a health care provider is immune from civil liability for injuries sustained by a person as a result of taking a drug or using a medical device if the health care provider prescribed or dispensed the drug or medical device for the person in accordance with: (1) instructions approved by the FDA; or (2) the standard of medical care in effect at the time the drug or medical device was prescribed or dispensed for the person.

Effective: July 1, 2005.

Torr

January 19, 2005, read first time and referred to Committee on Judiciary.

Introduced

First Regular Session 114th General Assembly (2005)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2004 Regular Session of the General Assembly.

HOUSE BILL No. 1672

A BILL FOR AN ACT to amend the Indiana Code concerning civil law and procedure.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 34-6-2-34.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 34.7. (a) "Drug", for purposes of IC 34-20-2-3.5 and IC 34-30-16.5, means a pharmaceutical product that must be approved by the FDA under:**

(1) the federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.); or

(2) Section 351 of the federal Public Health Service Act (21 U.S.C. 262).

(b) The term includes a biological product.

SECTION 2. IC 34-6-2-45.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 45.5. "FDA", for purposes of section 34.7 of this chapter, IC 34-20-2-3.5, and IC 34-30-16.5, refers to the federal Food and Drug Administration.**

SECTION 3. IC 34-6-2-54 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 54. (a) "Health care

provider", for purposes of IC 34-18 **and IC 34-30-16.5,** has the meaning set forth in IC 34-18-2-14.

(b) "Health care provider", for purposes of IC 34-30-12.5, has the meaning set forth in IC 34-30-12.5-2.

SECTION 4. IC 34-6-2-79.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 79.3. "Medical device", for purposes of IC 34-20-2-3.5 and IC 34-30-16.5, has the meaning set forth in 21 U.S.C. 321(h).**

SECTION 5. IC 34-20-2-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. Except as provided in ~~section~~ **sections** 3 **and 3.5** of this chapter, a person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property is subject to liability for physical harm caused by that product to the user or consumer or to the user's or consumer's property if:

(1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;

(2) the seller is engaged in the business of selling the product; and

(3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

SECTION 6. IC 34-20-2-3.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 3.5. (a) This section does not apply to the following manufacturers or sellers of drugs or medical devices:**

(1) A manufacturer or seller of a drug or medical device that fraudulently and in violation of applicable FDA regulations withholds information from or misrepresents information to the FDA that is material to the alleged harm a user or consumer of the drug or medical device suffered if the:

(A) FDA or a court, in an action brought by the federal government, makes a final determination that the manufacturer or seller fraudulently and in violation of applicable FDA regulations withheld the information from or misrepresented the information to the FDA; and

(B) withholding or misrepresentation of the information:

(i) occurred before; and

(ii) was causally related to;

the alleged harm the user or consumer suffered.

(2) A manufacturer or seller of a drug or medical device that sells the drug or medical device in the United States after the effective date of an FDA order to:

(A) remove the drug or medical device from the market; or

(B) withdraw FDA approval of the drug or medical device;

if the drug or medical device causes an injury to a user or consumer after the effective date of the FDA order.

(b) A manufacturer or seller of a drug or medical device is not subject to liability in a product liability action if:

(1) the FDA approved the drug or medical device as safe and effective under:

(A) Section 505, 512, or 515 of the federal Food, Drug and Cosmetic Act (21 U.S.C. 355, 21 U.S.C. 360b, or 21 U.S.C. 360e); or

(B) Section 351 of the federal Public Health Service Act (42 U.S.C. 262); and

(2) the FDA approval was in effect when the drug or medical device was sold to or for use by a user or consumer who was injured by the drug or medical device.

SECTION 7. IC 34-30-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]:

Chapter 16.5. Health: Immunity for Prescribing or Dispensing Drugs and Medical Devices

Sec. 1. A health care provider is immune from civil liability for injuries sustained by a person as a result of taking a drug or using a medical device prescribed or dispensed for the person by the health care provider if the health care provider prescribed or dispensed the drug or medical device in accordance with:

(1) instructions approved by the FDA concerning the dosage or administration of the drug or medical device, including the;

(A) indications for which the drug should be taken or medical device should be used; and

(B) contraindications against taking the drug or using the medical device; or

(2) the standard of medical care concerning the drug or medical device in effect at the time the drug or medical device was prescribed or dispensed for the person.